

Message Text

PAGE 01 STATE 203275

62

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 ISO-00 OES-05 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: MBEAUBIEN

DHEW/OIH: MACODDING

EUR/CE:DANDERSON (INFO)

EUR/WE:WMARSH (INFO)

AF/E:AESHIPPY (INFO)

ARA/NC:TSONANDRES (INFO)

EUR/NE:SWORREL (INFO)

ARA/CEN:PWACKERBARTH (INFO)

----- 030506

R 250015Z DEC 75

FM SECSTATE WASHDC

TO AMEMBASSY PARIS

AMEMBASSY BONN

AMEMBASSY TEGUCIGALPA

AMEMBASSY NAIROBI

AMEMBASSY LONDON

AMEMBASSY CARACAS

UNCLAS STATE 303275

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, FR, GW, HO, KE, UK, VE

SUBJECT: FDA ADVISORY - VOLUNTARY RECALL OF LABORATORY
CONTROL STANDARD DUE TO PRODUCT INSTABILITY

1. FDA ADVISES THAT:

PRODUCT:

LABELLED IN PART: "XXX 4C X NORMAL VALUES X COULTER
COUNTER X ALL CONTROL X HEMATOLOGY REFERENCE CONTROL XX
MANUFACTURED BY: COULTER DIAGNOSTICS, INC. X DISTRIBUTED
BY: COULTER ELECTRONICS, INC., HIALEAH, FLORIDA XXX".
UNCLASSIFIED

PAGE 02 STATE 203275

6/7 ML VIALS PER SET, 2/4 ML VIALS PER SET, OR 4/1 ML VIALS
PER SET.

LOT NUMBERS:

A. 6/7 ML SETS: 190, 192, 193, 267, 268, 276, 279, 281,
282, 284, 287, 288, 291, 292, 293, 296, 297, 298, 299, 300,
309, 372, 383, AND 384.

B. 2/4 ML SETS: 888, 889, 896

C. 4/1 ML SETS: 789, 791

MANUFACTURER/RECALLING FIRM:

COULTER DIAGNOSTICS, INC.
740 WEST 83RD STREET
HIALEAH, FLORIDA 33012

REASON FOR ADVISORY: THE FIRM'S QUALITY CONTROL ASSURANCE
DEPARTMENT ASSAYS FOUND THE LOTS TO BE OUTSIDE THE
ALLOWABLE 2SD (STANDARD DEVIATION) VARIANCE LIMITS FOR
RED BLOOD CELL (RBC) VALUES AND/OR MEAN CORPUSCULAR
VOLUME (MCV) VALUES PRIOR TO THE EXPIRATION DATE OF THE
LOTS. ALL THE LOTS WERE JUDGED TO BE UNSTABLE BY THE
FIRM, SINCE THESE ASSAYS SHOWED A PROGRESSIVELY RISING
VALUE FOR MCV DETERMINATIONS AND/OR A PROGRESSIVELY
DECLINING VALUE FOR RBC DETERMINATIONS.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE RECEIVED ADVISORY LETTERS
FROM COULTER DIAGNOSTICS, INC. DESCRIBING THE NATURE
OF THE PROBLEM WITH THE 4C NORMAL LABORATORY CONTROL
STANDARD AND ACTION TO BE TAKEN REGARDING UNSTABLE LOTS.
ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS
ADVISORY SHOULD BE REFERRED TO THE REGULATORY AFFAIRS
SECTION OF THE FIRM.

3. FOREIGN CONSIGNEES AS FOLLOWS:

COULTRONICS FRANCE S.A. LOTS 292 AND 309
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PAGE 03 STATE 203275

14 RUE EUGENE - LEGENORE
95 MARGENCY 95580
ANDILLY, FRANCE

KUEHNE AND NAGEL LOT 298
LUFTFRACHTGEBAUDE
ATTN: MR. KIENER
CIF COLOGN AIRPORT PORZ
WEST GERMANY

INST. HONDURENO DE SEGIURDAD LOT 789
SOCIAL JECUCIGALPA D.C.
HONDURAS CA

COULTER ELECTRONICS KENYA LTD. LOT 789
C/O KEARLINES, INC.
P.O. BOX 41564
NAIROBI, KENYA, EAST AFRICA

COULTER ELECTRONICS LTD. LOTS 292 AND 383
COLDHARBOUR LANE
HARPENDEN
HERTS ENGLAND AL54UN

COULTER ELECTRONICS S.A. LOT 383
ANTRO COMERCIAL CONCRESA
SEGUNDO PISO OFICINA 411
PRADOS DEL ESTE
CARACAS VENEZUELA S.A. KISSINGER

UNCLASSIFIED

<< END OF DOCUMENT >>

Message Attributes

Automatic Decaptioning: X
Capture Date: 18 AUG 1999
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: n/a
Control Number: n/a
Copy: SINGLE
Draft Date: 25 DEC 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1975STATE203275
Document Source: ADS
Document Unique ID: 00
Drafter: DHEW/FDA: JRWEINROTH, M.D.: AMS
Enclosure: n/a
Executive Order: N/A
Errors: n/a
Film Number: n/a
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1975/newtext/t19751290/abbrznzu.tel
Line Count: 127
Locator: TEXT ON-LINE
Office: n/a
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators:
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: KelleyW0
Review Comment: n/a
Review Content Flags:
Review Date: 23 MAY 2003
Review Event:
Review Exemptions: n/a
Review History: RELEASED <23 MAY 2003 by ReddocGW>; APPROVED <03 FEB 2004 by KelleyW0>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
06 JUL 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - VOLUNTARY RECALL OF LABORATORY CONTROL STANDARD DUE TO PRODUCT INSTABILITY
TAGS: OGEN, ETRD, TBIO, FR, GW, HO, KE, UK, VE
To: PARIS
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Type: TE

Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 06 JUL 2006